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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,292	03/23/2004	Robert Frost	029082.53212US	1862

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EXAMINER	
JASTRZAB, KRISANNE MARIE	
ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,292	FROST ET AL.	
	Examiner	Art Unit	
	Krisanne Jastrzab	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the use of "abruptly" is found to be vague and indefinite because it is a relative term of degree and it is unclear as to what would constitute "abruptly".

With respect to claims 3 and 4, the use of "warm" is found to be vague and indefinite because it is a relative term of degree and it is unclear as to what would constitute "warm".

With respect to claim 8, the use of "rapid" and "hot" are found to be vague and indefinite because they are relative terms of degree and it is unclear as to what would constitute "rapid" or "hot".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cummings et al., U.S. patent No. 4,952,370.

Cummings et al., teach sterilization of the surfaces of a chamber wherein a combination of steam and hydrogen peroxide is created in a vaporizer, the combination is sent to the chamber to be sterilized and then condensed on the surfaces being treated. A vacuum is drawn to remove the condensate by evacuation. The vacuum is set such that the water vapor will removed first to enhance contact of the hydrogen peroxide. The steps of the process are repeated with the introduction of the hydrogen peroxide/steam combination occurring in a plurality of injections. See column 2, lines 40-53, column 3, lines 40-68, column 4, lines 45-62, column 5, lines 20-30, column 6, lines 1-5, 12-16, 20-25, 33-50 and 65-68, and column 7, lines 1-5.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Koubek U.S. patent No. 4,512,951.

Koubek teaches the application of a combination of steam and hydrogen peroxide, condensed onto surfaces of surgical and diagnostic articles to be sterilized with the removal there of via the application of vacuum. Koubek teaches preheating of the system to prevent premature condensation of the combination before contacting all surfaces. See column 1, lines 13-15, column 3, lines 35-30 and column 4, lines 15-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al., '370 as applied to claims 1-6 and 8 above, and further in view of Pflug et al., U.S. patent No. 5,525,295.

Pflug et al. teach a similar sterilization method as that in Cummings utilizing a combination of steam and hydrogen peroxide. Pflug et al., further teach the use of conveying systems for moving articles into and out of the sterilization chamber to be

treated without requiring direct user contact before or after the treatment. See column 4, lines 1-7, column 5, lines 4-37, column 9, lines 38-45.

It would have been well within the purview of one or ordinary skill in the art to employ conveying means as in Pfug et al., with a sterilization method as in Cummings et al., if sterilizing objects as well as chamber surfaces, because it would optimally provided for transport of the articles into and out of the treatment area without compromising the integrity of the treatment area sterility, and without requiring direct user contact.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/363,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of the same inventive concept, namely, sterilization by the application of steam and hydrogen peroxide such

that they condense onto the surface being sterilized, with removal thereof by drawing a vacuum, differentiated only by '546 claiming placement of the object in a known and well recognized sterilization wrap or bag.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/759,071. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of the same inventive concept, namely, sterilization by the application of steam and hydrogen peroxide such that they condense onto the surface being sterilized, with removal thereof by drawing a vacuum, differentiated only in that '071 specifies that the sterilization chamber be constructed of non-heat conducting materials which is intrinsic to the process requiring condensation of the sterilant onto those surfaces.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/941,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of the same inventive concept, namely, sterilization by the application of steam and hydrogen peroxide such that they condense onto the surface being sterilized, with removal thereof by drawing a

vacuum, differentiated only by '292 claiming pre-heating of surfaces in the treatment area, a well recognized step in processes employing the injection of a previously vaporized sterilant in order to ensure that the sterilant reaches the entire area before condensing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 2/22/2005 have been fully considered but they are not persuasive.

Applicant argues that the claim recitations of terms such as "abruptly", "warm" and "hot" are sufficiently supported by the instant specification and refer to a definition of abrupt as defined in paragraph 003 thereof to be a few tenths of a second to a maximum of a few seconds, however, the Examiner would point out that this recitation is discussing prior art in the background of the invention and fails to properly provide basis for Applicant's use of the term within the claims. Applicant further argues that sufficient background was cited in the specification for one of ordinary skill in the art to determine temperatures which would meet "warm" and "hot", however, the Examiner would disagree and maintain those rejections because the temperatures that are recited in the specification are temperatures of the objects not the "warm air" that is claimed.

Applicant further argues that Cummings fails to meet the claimed limitations because it teaches an introduction of hydrogen peroxide vapor for approximately one minute (column 6) which does not equate to "rapidly expanding", however, the Examiner

would maintain that such introduction into a pre-evacuated sterilization chamber and achieving the instantly claimed condensation of the vapor, does meet the "rapidly expanding" limitation as it has not been defined in a manner to exclude the teachings of Cummings.

Applicant also argues that the process of Koubek is not a "rapid" process, however, the Examiner would point out that Koubek clearly teaches all of the same steps as set forth in the invention, evacuation of the chamber, introduction of the vaporized hydrogen peroxide/steam mixture, condensation of that mixture and evacuative removal thereof. The walls of the chamber are pre-heated to 100 °F to ensure that the article remains at a temperature just below the condensation temperature of hydrogen peroxide. It is held by the Examiner that a process time of minutes as disclosed in Koubek would certainly be "rapid".

Applicant finally argues that the obviousness-type double patenting rejections are not proper because none of the claims would literally infringe the others and the inventions are patentably distinct, however, the Examiner would disagree for the reasons cited in the rejection and Applicant has not clearly provided any basis for a non-obvious patentable distinction between the claimed inventions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krisanne Jastrzab
Primary Examiner
Art Unit 1744

May 16, 2005